

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : Dotan, *et al.* CONFIRMATION No. : 7868
SERIAL NUMBER : 10/634,309 EXAMINER : Gerald R. Ewoldt
FILING DATE : August 4, 2003 ART UNIT : 1644
FOR : METHOD FOR DIAGNOSING MULTIPLE SCLEROSIS

Mail Stop: Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT
UNDER 37 C.F.R. §1.705(d)

Applicants request reconsideration of patent term adjustment for the above-referenced application. Also enclosed is the two-hundred dollar fee as required by 37 C.F.R. § 1.18(e).

The above-reference application issued on May 26, 2009. The total patent term adjustment calculated by the Patent Office under 35 U.S.C. §154(b) is 436 days, which is recited on the face of the above-referenced application. By this paper, Applicants hereby petition the U.S. Patent and Trademark Office for reconsideration of the patent term adjustment calculation to **991 days**, based on the facts provided herein. This Request is submitted in view of the decision by the U.S. District Court decision in *Wyeth v. Dudas* (D.D.C. 2008) on September 30, 2008.

This patent application was filed on August 4, 2003, and is therefore subject to the patent term adjustment procedures set forth in 37 C.F.R. §§ 1.702 to 1.705 for applications filed on or after May 29, 2000.

On November 4, 2003, the Office mailed a Notice to File Missing Parts of Non-Provisional Application.

On December 2, 2003, Applicants filed a Response to the Notice to File Missing Parts. This response was received by the Office within three-months of the mailing date of the action.

On April 10, 2006, the Office mailed a Restriction/Election-of-Species. The Action was mailed 553 days after the fourteen month requirement for mailing of the first action after the date

on which the application was filed under 35 USC §111(a). As shown in the PAIR printout included as Exhibit A, the number of days of Patent Term Adjustment accounts for the 553 day Office delay.

On May 10, 2006, Applicants filed a Response to Election-of-Species/Restriction. This response was received by the Office within three-months of the mailing date of the action.

On July 25, 2006, the Office mailed a Non-Final Office Action.

On October 25, 2006, Applicants filed a Response to the Non-Final Office Action, which, as noted by the Office in the Notice of Non-Compliant Amendment mailed on January 9, 2007, did not include the text of all the claims. Therefore, Applicants filed a second Response to the Non-Final Office Action on January 25, 2007. This Response was filed 84 days after the date that is three months after the mailing date of the Non-Final Office Action. As shown in Exhibit A, the number of days of Patent Term Adjustment accounts for the 84 day Applicant delay.

On November 1, 2007, the Office mailed a Final Office Action. This Action was mailed 168 days after the date that is four months after the date on which the previous reply was filed. As shown in Exhibit A, the number of days of Patent Term Adjustment accounts for the 168 day Office delay.

On May 1, 2008, Applicants filed a Response to the Final Office Action and a Request for Continued Examination with a Petition for a three month extension of time. This response was filed 90 days after the date that is three months after the mailing date of the Final Office Action. As shown in Exhibit A, the number of days of Patent Term Adjustment accounts for the 90 day Applicant delay.

On July 15, 2008, the Office mailed a Non-Final Office Action.

On October 15, 2008, Applicants filed a Response to the Non-Final Office Action. This response was received by the Office within three-months of the mailing date of the action.

On January 27, 2009, the Office mailed the Notice of Allowance/Notice of Allowability, and the Determination of Patent Term Adjustment for this application. The Determination of Patent Term Adjustment noted an adjustment period for this patent application of 547 days.

On February 5, 2009, Applicants paid the Issue Fee payment.

On February 5, 2009, Applicants filed an Amendment After Notice of Allowance under 37 CFR 1.312.

On February 27, 2009, the Office mailed a Response to Rule 312 Communication. This Response was mailed 23 days after the date the Amendment After Notice of Allowance was filed. As such, Applicants submit that an additional 23 days of Applicant delay should noted.

According to the provisions of 37 C.F.R. §1.702(b), Applicants are entitled to Patent Term Adjustment for the failure of the Office to issue the patent within three years after the date on which the application was filed. Under 37 C.F.R. §1.702(b)(1)-(5), Applicants are entitled to this adjustment for any time other than any time consumed by continued examination of the application requested by the applicant under section 132(b), beginning on the date on which a Request for Continued Examination was filed, May 1, 2008, and ending on the date the patent issues.

The amount of the Adjustment under 37 C.F.R. §1.702(b) is calculated from August 5, 2006 (*i.e.*, the day after the date that is three years from the date that the application was filed), through and including April 30, 2008, the day before the date the Request for Continued Examination was filed, subtracting only time legitimately attributable to applicant delay. Applicants submit that the Adjustment under 37 C.F.R. §1.702(b) is 635 days. However, the delay under 37 C.F.R. §1.702(b) overlaps with delay under 37 C.F.R. 1.702(a) from May 18, 2007 through November 1, 2007, which is a total of 168 days of overlap. Therefore the Adjustment under 37 C.F.R. §1.702(b) is 635 days - 168 days of overlap = 467 days.

Applicants have calculated the Patent Term Adjustment based on 37 C.F.R. 1.702(a), 37 C.F.R. 1.702(b) and 37 C.F.R. 1.704 through the Issue Date of May 26, 2009. Applicants submit that an additional 467 days of Office delay should be included, under 37 C.F.R. 1.702(b), in calculating the total Patent Term Adjustment. Accordingly, the total calculation of Patent Term Adjustment is as follows: Office delay under 37 CFR 1.702(a) is 721 days; Office Delay under 37 CFR 1.702(b) is 467 days; and Applicant delay under 37 CFR 1.704(c) is: $84+90+23=197$ days; adjustment: $(721+467-197) = 991$ days.

Applicants respectfully request that the Patent Term Adjustment be increased from 436 days, as reported on the Determination of Patent Term Adjustment under 35 U.S.C. 154 (b), to **991 days**.

In addition to the foregoing, a Terminal Disclaimer was filed on October 15, 2008 directed to US Application No. 10/835,607.

If the Office would like to discuss any aspect of this filing, the Office representative assigned to process this request is welcome to call the undersigned attorneys. No additional fees are believed to be due by submission of this paper. However, the Office is authorized to charge such fee, or credit any overpayment in fees to Deposit Account No. **50-0311**, Customer Number **30623**, Attorney Docket No. 25681-501.

Respectfully submitted,



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Date: July 24, 2009

Exhibit A

10/634,309	METHOD FOR DIAGNOSING MULTIPLE SCLEROSIS	07-24-2009::13:45:23
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Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 10/634,309

Filing or 371(c) Date:	08-04-2003	USPTO Delay (PTO) Delay (days):	721
Issue Date of Patent:	05-26-2009	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	285
Post-Issue Petitions (days):	+0	Total PTA (days):	436
USPTO Adjustment(days):	+0	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
05-06-2009	PTA 36 Months		
05-26-2009	Patent Issue Date Used in PTA Calculation		
03-03-2009	Dispatch to FDC		
02-26-2009	Application Is Considered Ready for Issue		
02-27-2009	Mail Response to 312 Amendment (PTO-271)		
02-24-2009	Response to Amendment under Rule 312		
02-23-2009	Receipt into Pubs		
02-05-2009	Amendment after Notice of Allowance (Rule 312)		
02-05-2009	Workflow - Drawings Finished		111
02-05-2009	Issue Fee Payment Verified		
02-05-2009	Issue Fee Payment Received		
02-04-2009	Receipt into Pubs		
01-27-2009	Mail Notice of Allowance		
01-22-2009	Document Verification		
01-22-2009	Notice of Allowance Data Verification Completed		
11-04-2008	Paralegal TD Accepted		
10-15-2008	Terminal Disclaimer Filed		
10-15-2008	terminal disclaimer fee paid		
11-03-2008	Date Forwarded to Examiner		
10-15-2008	Response after Non-Final Action		
05-21-2008	Miscellaneous Incoming Letter		
07-15-2008	Mail Non-Final Rejection		
07-09-2008	Non-Final Rejection		
05-09-2008	Date Forwarded to Examiner		
05-09-2008	Date Forwarded to Examiner		
05-01-2008	Request for Continued Examination (RCE)		90
05-09-2008	DISPOSAL FOR A RCE/CPA/129 (express abandonment if CPA)		⬆
05-01-2008	Request for Extension of Time - Granted		⬆
05-01-2008	Workflow - Request for RCE - Begin		⬆
05-05-2008	Mail Examiner Interview Summary (PTOL - 413)		⬆

05-01-2008	Examiner Interview Summary Record (PTOL - 413)		↑
11-01-2007	Mail Final Rejection (PTOL - 326)	168	
10-29-2007	Final Rejection	↑	
08-16-2007	Date Forwarded to Examiner	↑	
01-17-2007	Response after Non-Final Action		84
01-09-2007	Mail Notice of Informal or Non-Responsive Amendment		↑
10-25-2006	Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received		↑
11-14-2006	Date Forwarded to Examiner		↑
10-25-2006	Informal or Non-Responsive Amendment after Examiner Action		↑
10-25-2006	Response after Non-Final Action		↑
07-25-2006	Mail Non-Final Rejection		
07-20-2006	Non-Final Rejection		
05-18-2006	Date Forwarded to Examiner		
05-10-2006	Response to Election / Restriction Filed		
04-10-2006	Mail Restriction Requirement	553	
04-03-2006	Requirement for Restriction / Election	↑	
03-15-2006	Information Disclosure Statement considered	↑	
02-20-2004	Information Disclosure Statement considered	↑	
02-05-2004	Information Disclosure Statement considered	↑	
03-15-2006	Reference capture on IDS	↑	
03-15-2006	Information Disclosure Statement (IDS) Filed	↑	
03-15-2006	Information Disclosure Statement (IDS) Filed	↑	
05-12-2005	Miscellaneous Incoming Letter	↑	
10-18-2004	Preliminary Amendment	↑	
10-18-2004	Workflow incoming amendment IFW	↑	
02-20-2004	Information Disclosure Statement (IDS) Filed	↑	
02-20-2004	Information Disclosure Statement (IDS) Filed	↑	
02-05-2004	Information Disclosure Statement (IDS) Filed	↑	
02-05-2004	Information Disclosure Statement (IDS) Filed	↑	
02-26-2004	IFW TSS Processing by Tech Center Complete	↑	
12-02-2003	Oath or Declaration Filed (Including Supplemental)	↑	
02-26-2004	Case Docketed to Examiner in GAU	↑	
01-13-2004	Application Return from OIPE	↑	
01-13-2004	Application Return TO OIPE	↑	
01-13-2004	Application Dispatched from OIPE	↑	
01-13-2004	Application Is Now Complete	↑	
12-02-2003	Additional Application Filing Fees	↑	
12-02-2003	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic	↑	
11-04-2003	Notice Mailed--Application Incomplete--Filing Date Assigned	↑	

10-21-2003	Cleared by OIPE CSR	⬆
09-18-2003	IFW Scan & PACR Auto Security Review	⬆
08-04-2003	Initial Exam Team nn	⬆

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